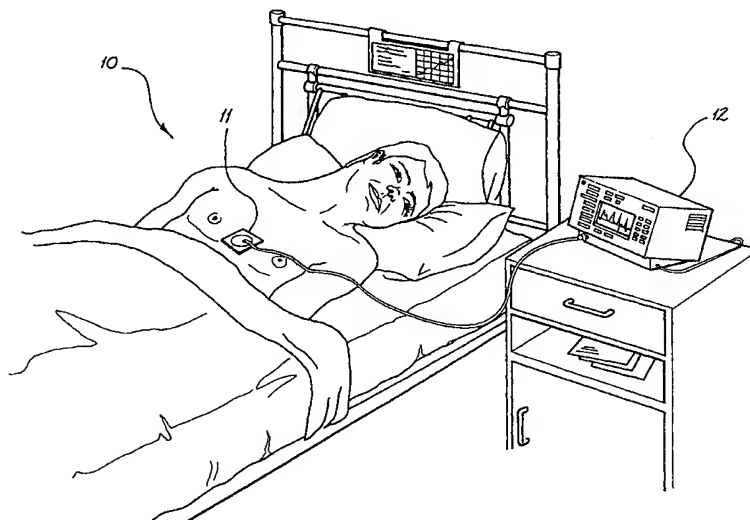




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61B 5/024, 5/029, 8/02, 8/06</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 99/66835</b> <b>(43) International Publication Date:</b> 29 December 1999 (29.12.99)
<b>(21) International Application Number:</b> PCT/AU99/00507 <b>(22) International Filing Date:</b> 23 June 1999 (23.06.99) <b>(30) Priority Data:</b> PP 4318                      24 June 1998 (24.06.98)                      AU <b>(71) Applicant (for all designated States except US):</b> NORTHERN CARDIAC SONOGRAPHY PTY. LTD. [AU/AU]; P.O. Box J241, Coffs Harbour, NSW 2450 (AU). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> PHILLIPS, Robert [AU/AU]; P.O. Box J241, Coffs Harbour, NSW 2450 (AU). <b>(74) Agent:</b> FREEHILLS PATENT ATTORNEYS; Level 34, MLC Centre, Martin Place, Sydney, NSW 2000 (AU).		<b>(81) Designated States:</b> AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** ULTRASONIC CARDIAC OUTPUT MONITOR



**(57) Abstract**

A method of cardiac physiologic monitoring is disclosed comprising the steps of: (a) utilising an external ultrasonic transducer element attached to a patient to determine an information signal indicative of blood flow within a patient's heart; (b) processing the information signal to determine physiologic parameters associated with the heart. The physiologic parameters can include at least one of transaortic peak velocity, mean transvalvular pressure gradient, time velocity integral, stroke volume, cardiac output or any other product as an analogue of output. The method can preferably include monitoring the change in time of the physiologic parameters through continual monitoring of the information signal. The monitoring step preferably can include determining an alarm state if the parameters are preferably outside a predetermined range. The external ultrasonic transducer preferably can include an attached handle operative to position the transducer in a predetermined orientation to the patient's heart.

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## ULTRASONIC CARDIAC OUTPUT MONITOR

### Field of the Invention

The present invention relates to the field of cardiac monitoring and, in particular, discloses a method for  
5 utilisation of an external transducer element in ultrasonic cardiac monitoring.

### Background of the Invention

The process of accurate cardiac physiologic monitoring is obviously an important process during acute illness and  
10 anaesthesia. In particular, early detection of changes in cardiac function can be critical in the reduction of patient morbidity and mortality.

Current methods of direct cardiac monitoring are expensive, technically difficult to operate and provide for  
15 variable results.

One common form of monitoring is the electrocardiographic method which monitors the electrical cardiac activity. Unfortunately, this method only provides for an indirect monitoring of cardiac muscle conductivity and not  
20 blood flow. Also currently utilised is an ultrasonic method of cardiac physiologic monitoring utilising 2D transoesophageal echocardiographic ventricular transections. However, this method is invasive, expensive and inaccurate by virtue of its technical difficulty and  
25 that only 6 of 16 myocardial segments are imaged at any time. Unfortunately, normal left ventricular myocardial function varies transmurally, transtemporally and intersegmentally and the 2D evaluation of the wall motion requires spatial and temporal integration skills only  
30 acquired after a programme of extensive and expensive physician training.

There is therefore a general need for an improved, more convenient form of cardiac physiologic monitoring.

### Summary of the Invention

35 It is an object of the present invention to provide

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for an improved form of cardiac physiologic monitoring utilising ultrasound techniques.

In accordance with a first aspect of the present invention, there is provided a method of cardiac

5 physiologic monitoring comprising the steps of:

(a) utilising an external ultrasonic transducer element attached to a patient to determine an information signal indicative of blood flow within a patient's heart;

(b) processing the information signal to determine  
10 physiologic parameters associated with the heart function.

The physiologic parameters can include at least one of transaortic peak velocity, mean transvalvular pressure gradient, time velocity integral, stroke volume, cardiac output or any other product as an analogue of output.

15 The method can preferably include monitoring the change in time of the physiologic parameters through continual monitoring of the information signal.

The monitoring step preferably can include determining an alarm state if the parameters are outside a  
20 predetermined range.

The external ultrasonic transducer preferably can include an attached handle operative to position the transducer in a predetermined orientation to the patient's heart.

25 In accordance with a further aspect of the present invention, there is provided a cardiac monitoring system comprising: an external ultrasonic transducer element adapted to be attached to a patient to provide an information signal indicative of blood flow within a  
30 patient's heart; computer processing means, interconnected to the transducer element and adapted to process the information signal to determine physiologic parameters associated with the heart.

The physiologic parameters can include at least one of  
35 transaortic peak velocity, mean transvalvular pressure

gradient, time velocity integral, stroke volume, cardiac output or any other product as an analogue of flow.

#### Brief Description of the Drawings

Notwithstanding any other forms which may fall within the scope of the present invention, preferred forms of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 illustrates an example output of a ventricular insonation;

Figs. 2 and 3 illustrate various features of the output of Fig. 1;

Fig. 4 is a perspective view of an arrangement of the preferred embodiment when utilised to monitor a patient;

Fig. 5 illustrates a sectional view of the transducer element;

Fig. 6 is a functional block diagram of the preferred embodiment; and

Fig. 7 illustrates an example form of user interface suitable for use with the preferred embodiment.

#### Description of Preferred and Other Embodiments

In the preferred embodiment, simple Doppler echocardiographic evaluation of cardiac blood flow is utilised to provide accurate and reproducible cardiac output information which allows for the utilization of equipment that is simple in design, durable, inexpensive to manufacture and easy to operate.

In the preferred embodiment, transaortic and transpulmonary continuous wave (CW) Doppler analysis is adapted for use as a heart monitoring device. Continuous wave Doppler is well validated and a routine echocardiographic method of quantitating cardiac output with low inter and intra observer variability.

Turning to Fig. 1, there is illustrated an example CW screen grab output 1 from a 7777 device which provides for a measure of blood velocity over time. The CW method

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detects the velocity of individual blood cells by measuring the frequency change of a reflected ultrasound beam and displaying this as a time velocity flow profile as indicated in Fig. 1.

5       Appropriately directed Doppler insonation from the apical or suprasternal acoustic window provides a time velocity profile of transaortic flow, while insonation from the parasternal window provides a transpulmonary flow profile. This flow profile is an analogue of cardiac  
10       output and is a real time stroke to stroke measure of cardiac physiology.

          The preferred embodiment utilizes the flow profile to generate a corresponding change monitoring of the flow profile with time. The spectral flow profile can be image  
15       processed to be accurately edge detected, providing a real time computed read out of transaortic peak velocity (Vpk) Heart Rate (HR), means transvalvular pressure gradient (Pmn), time velocity integral (tvi) and, with a premeasured aortic (Ao) or pulmonary artery (PA) diameter from a 2D  
20       examination, cardiac output (CO) or any other product as an analogue of output can be determined. The measures (Vpk), tvi and HR are illustrated in Fig. 2.

          Intracardiac flow across the aortic valve and the pulmonary valve must be equal in the absence of significant  
25       regurgitation or trans-septal flow (shunt), and regardless, both can be used to reflect changes in cardiac output, so the choice of whether transpulmonary or transaortic monitoring is chosen can depend only on the ease of signal access.

30       Although absolute flow can be determined using aortic valve or pulmonary artery diameter derived from a 2D echocardiogram, this may not be required as the relevance of physiologic monitoring is dependent on detecting temporal changes in output. Therefore, a change from  
35       either the baseline transaortic or transpulmonary profile

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would, providing there was no significant change in the angle of insonation, represent a change in output proportional to the change in the baseline parameters (tvi, Pmn, Vpk and CO) etc.

5           In the preferred embodiment normal variance ranges for haemodynamic parameters can be preferably user selected from the reference cycles so that an alarm would sound if signals exceeded this range. As illustrated in Fig. 3, the tolerance for alarm activation for (Vpk) could be a stepped  
10 user selected variable set to compensate for individual baseline stroke to stroke variability (-15%, -20%, -30% etc).

          Arrhythmias are associated with cardiac disease and can produce high stroke to stroke variability of  
15 haemodynamic parameters making automated single cycle signal analysis unrepresentative. This can be addressed using multi cycle signal averaging so that a user selected variable number of cycles would be averaged to give mean Vpk, Pmn, tvi and CO parameters for alarm detection and the  
20 setting of wide alarm parameters for stroke to stroke variability.

          The direct measurement of transpulmonary flow can be achieved by applying a small CW transducer with an adherent gel coupling layer to the surface of the skin at the left  
25 parasternal acoustic window; adjacent to the sternum in an intercostal interspace, while the transaortic flow can be detected from the intercostal space associated with the palpable ventricular apex beat or from the suprasternal notch. The transducer can be fixed in place with adhesive  
30 tape or sheet and or a transthoracic belt utilising a thin gel coupling layer to ensure transducer skin contact.

          In Fig. 4 there is illustrated an example arrangement with a patient 10 being monitored utilising a transducer element 11 interconnected with a computer signal processing  
35 unit 12.

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In Fig. 5, there is illustrated an enlarged sectional view of the transducer element 11 which includes a transducer 15 attached to a positioning device 16 which can be utilised to initially set the position of the  
5 transducer. Between the transducer 15 and a person's skin 17 is placed a gel coupling layer 18 for coupling the ultrasonic transducer vibrations to the skin 17.

Turning now to Fig. 6, there is illustrated, in functional block diagram form, one form of construction of  
10 the computer system 12 of Fig. 4. The system 12 includes a master oscillator 20 which is interconnected to a transmitter 21 which is responsible for transmitting the oscillation to transducer 11. The transducer 11 includes receiver 22 which is forwarded to a demodulating element 23  
15 which utilises phase outputs from the master oscillator 20 so as to demodulate the received signal from receiver 22 so as to provide for a spectral output which is forwarded to a spectral analyser 24 which can in turn include a computer digital signal processor arrangement for processing the  
20 output signal so as to determine the relevant parameters. The spectral analyser 24 can comprise a computer type device with appropriate DSP hardware. The spectral analyser 24 outputs to a spectral display 25 which can include a standard user interface of relevant information.  
25 For example, in Fig. 7, there is shown an example display output which includes buttons for setting various sensitivity and alarm ranges so as to provide for full cardiac physiologic monitoring.

The continuous wave ultrasound transducer (1.0 to  
30 3.0Mhz) 11 can include a small raised toggle for angular adjustment. The transducer can be strapped to the left ventricular apical intercostal window, the left parasternal intercostal window or the suprasternal notch and fixed in place with an adhesive sheet or tape, and a belt.

35 Turning now to Fig. 8, there is illustrated the steps



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involved in the method of requisite features extraction by the DSP processor. The steps 30 rely on standard image processing techniques well known to those skilled in the art of computer image processing.

5           Initially, a first CW image is captured 31. From this image, the edges are extracted 32 and analyzed so as to determine the relevant parameters 33. By repeating the process 31-33 for multiple frames, it is possible to determine variations in time base parameters 34. These  
10 variations can be saved 35 or output 36 for display and monitoring.

Obviously, many different arrangements of a system are possible. The system could be utilised as a stand alone physiologic monitor, integrated with oximetry, ECG etc or  
15 to provide for a remote monitor with on-board analysis or remote transmission.

It would be appreciated by a person skilled in the art that numerous variations and/or modifications may be made to the present invention as shown in the specific  
20 embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects to be illustrative and not restrictive.

We Claim:

1. A method of cardiac physiologic monitoring comprising the steps of:

(a) utilising an external ultrasonic transducer element attached to a patient to determine an information signal indicative of blood flow within a patient's heart;

(b) processing said information signal to determine physiologic parameters associated with the heart.

2. A method as claimed in claim 1 wherein said physiologic parameters include at least one of transaortic peak velocity, mean transvalvular pressure gradient, time velocity integral, stroke volume, cardiac output or any other product as an analogue of output.

3. A method as claimed in claim 1 further comprising the step:

(c) monitoring the change in time of said physiologic parameters through continual monitoring of said information signal.

4. A method as claimed in claim 3 wherein said monitoring step includes determining an alarm state if said parameters are outside a predetermined range.

5. A method as claimed in claim 1 wherein said external ultrasonic transducer includes an attached handle operative to position said transducer in a predetermined orientation to said patient's heart.

6. A cardiac monitoring system comprising:  
an external ultrasonic transducer element adapted to be attached to a patient to and to provide an information signal indicative of blood flow within a patient's heart;  
computer processing means, interconnected to said transducer element and adapted to process said information signal to determine physiologic parameters associated with the heart.

7. A cardiac monitoring system as claimed in claim 6 wherein said physiologic parameters include at least one of

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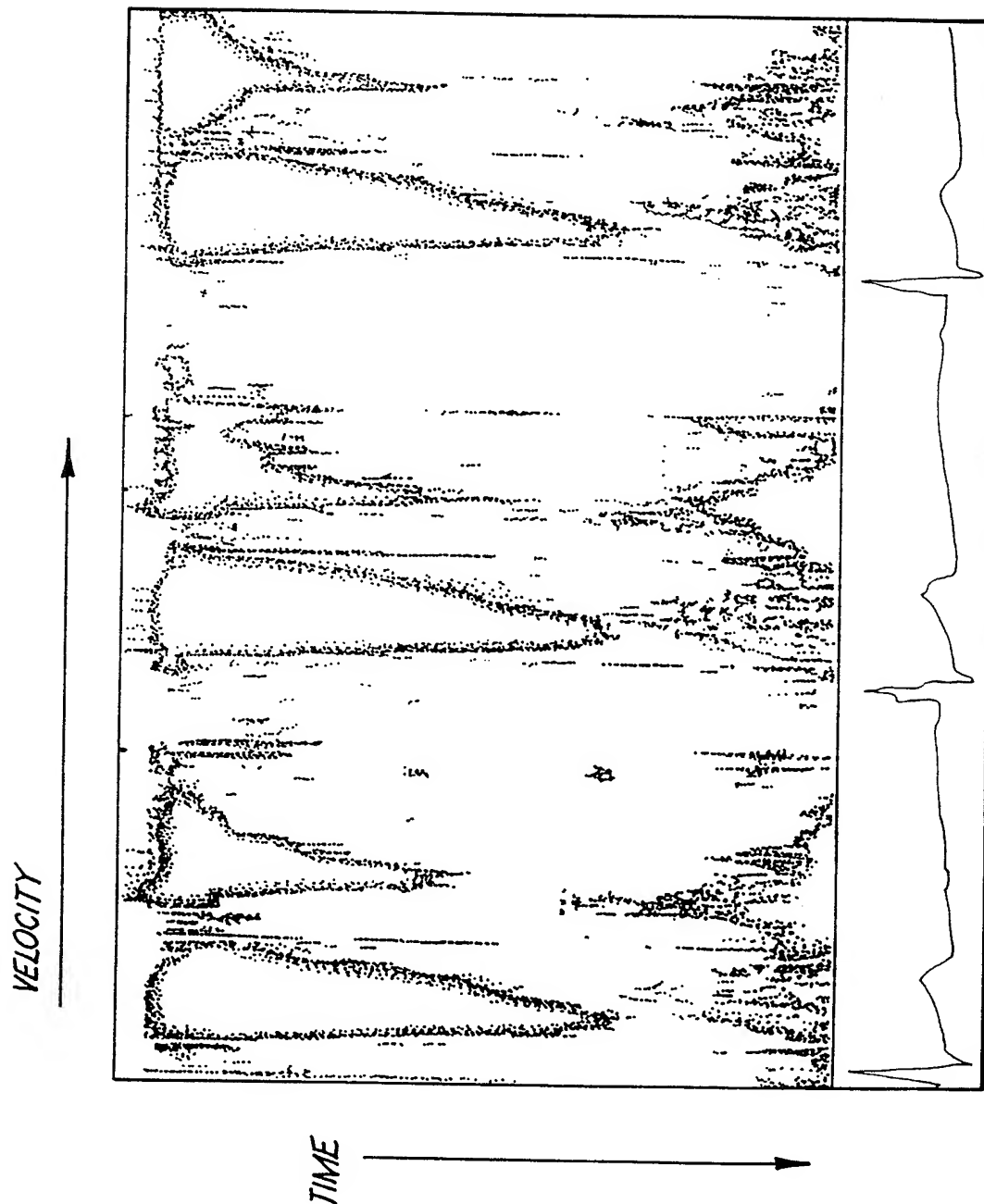
transaortic peak velocity, mean transvalvular pressure gradient, time velocity integral, stroke volume, cardiac output or any other product as an analogue of output.

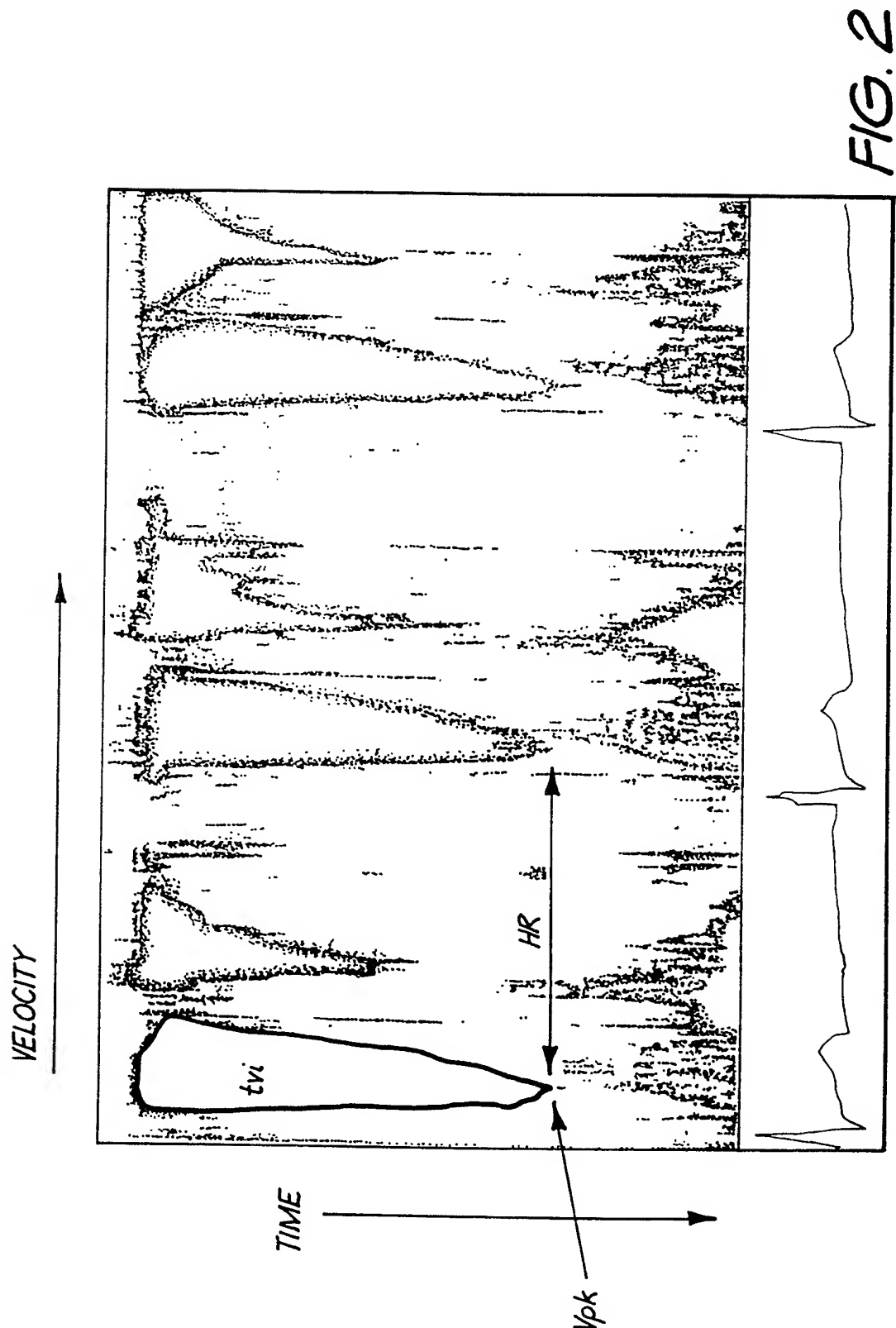
8. A cardiac monitoring system as claimed in claim 6  
5 further comprising:

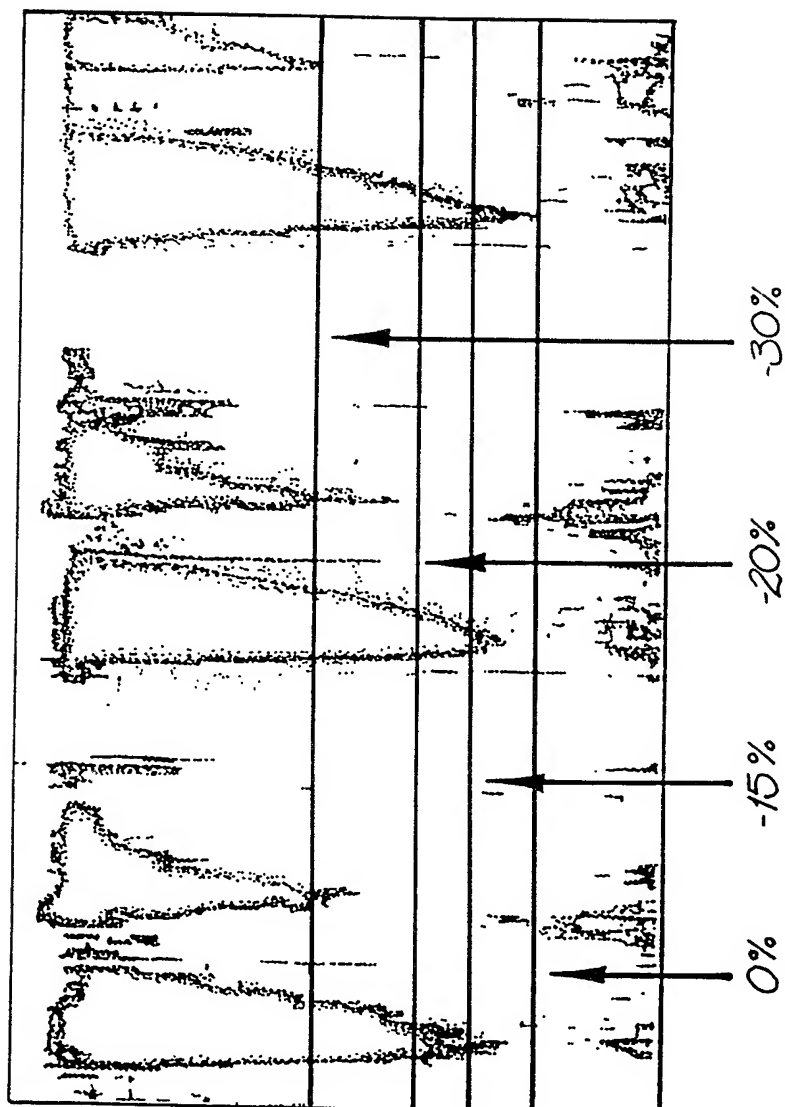
alarm means interconnected to said computer processing means and adapted to emit an alarm if said parameters are outside a predetermined range.

9. A cardiac monitoring system as claimed claims 6  
10 wherein said external ultrasonic transducer element includes an attached handle operative to position said transducer in a predetermined orientation to said patient's heart.

FIG. 1







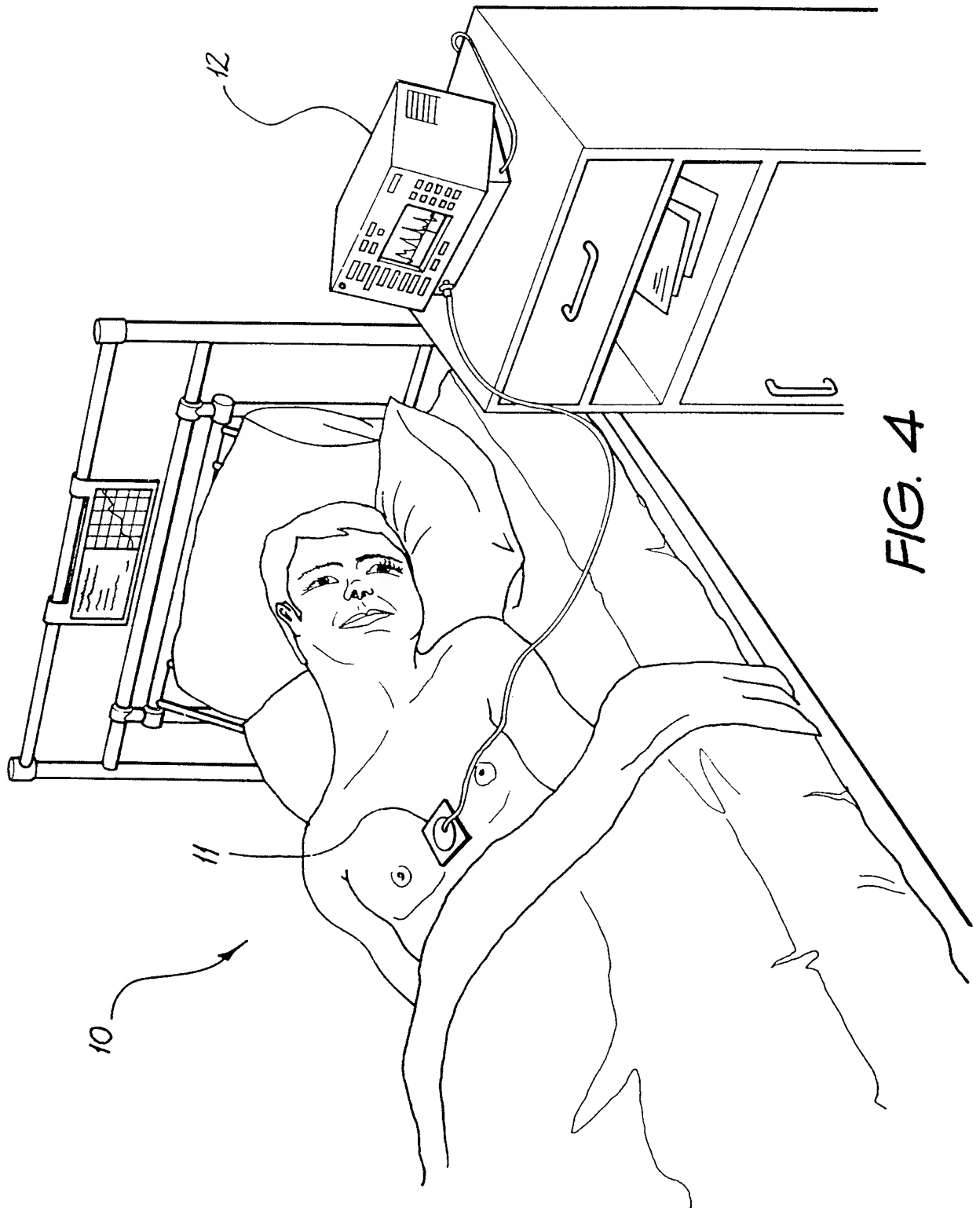


FIG. 4

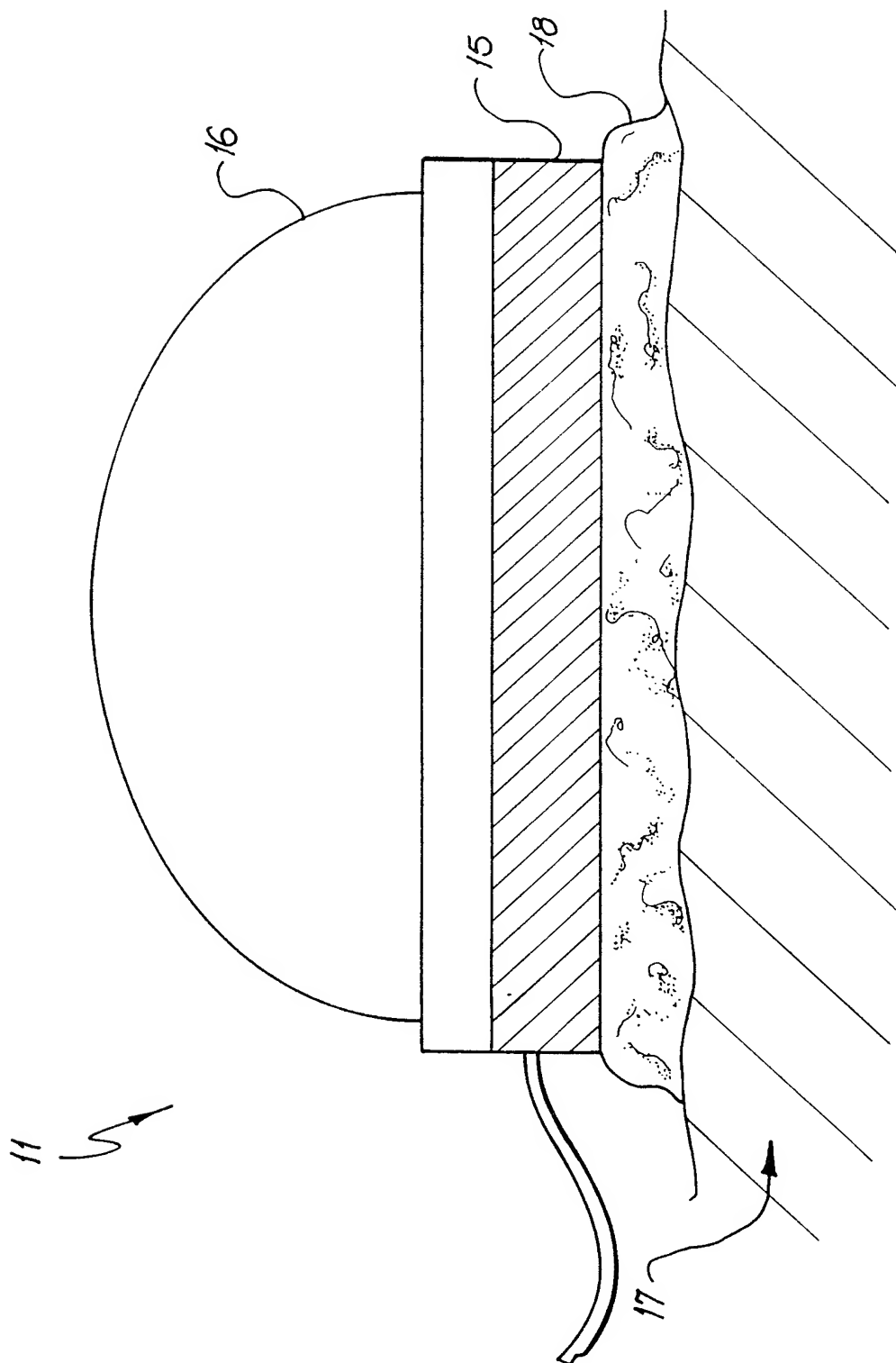


FIG. 5



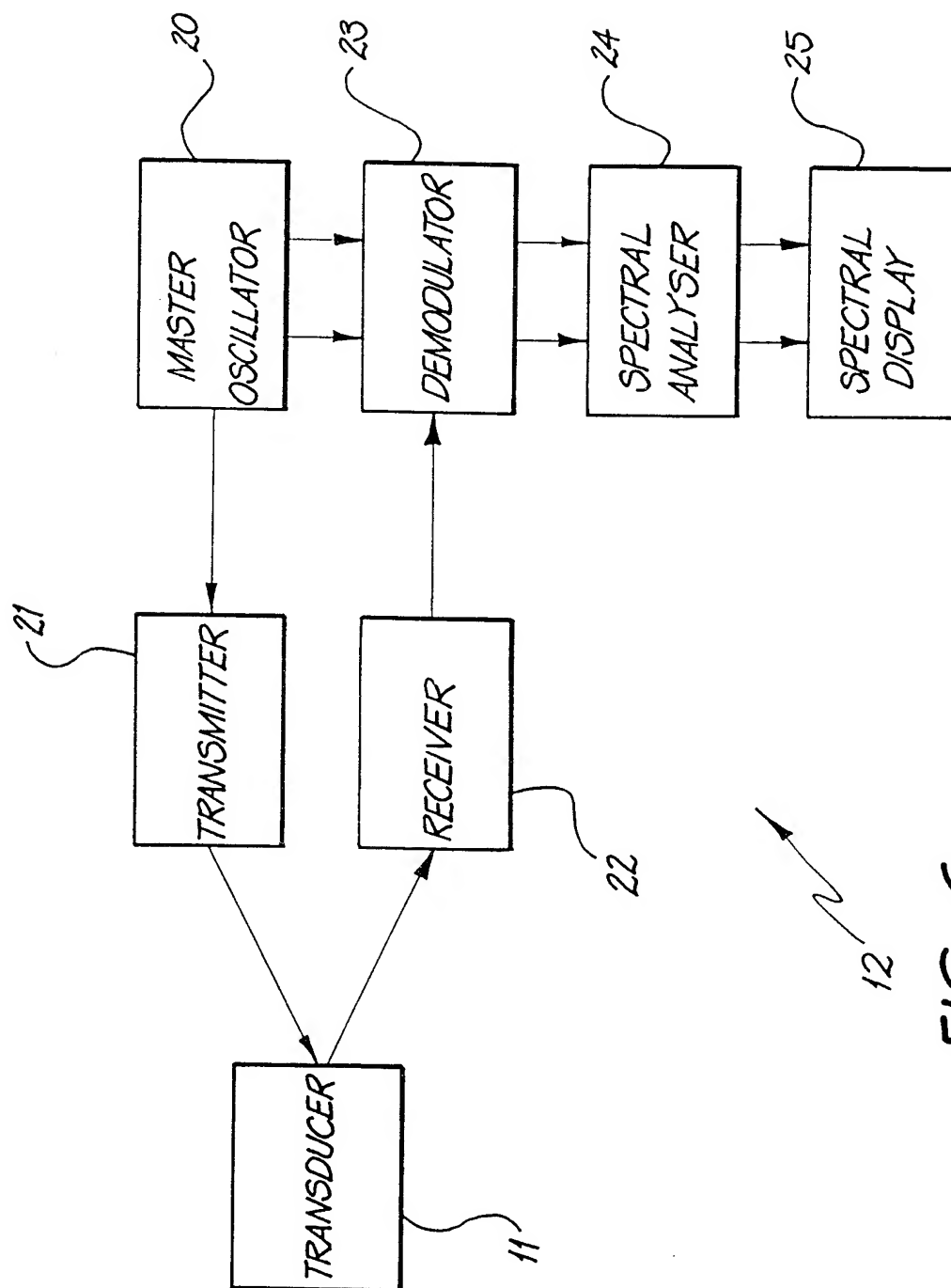


FIG. 6

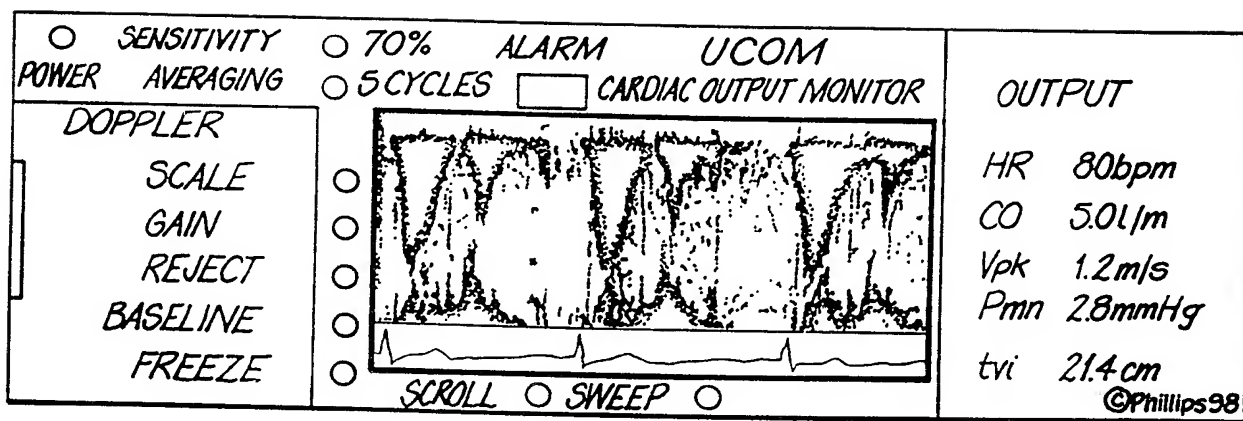
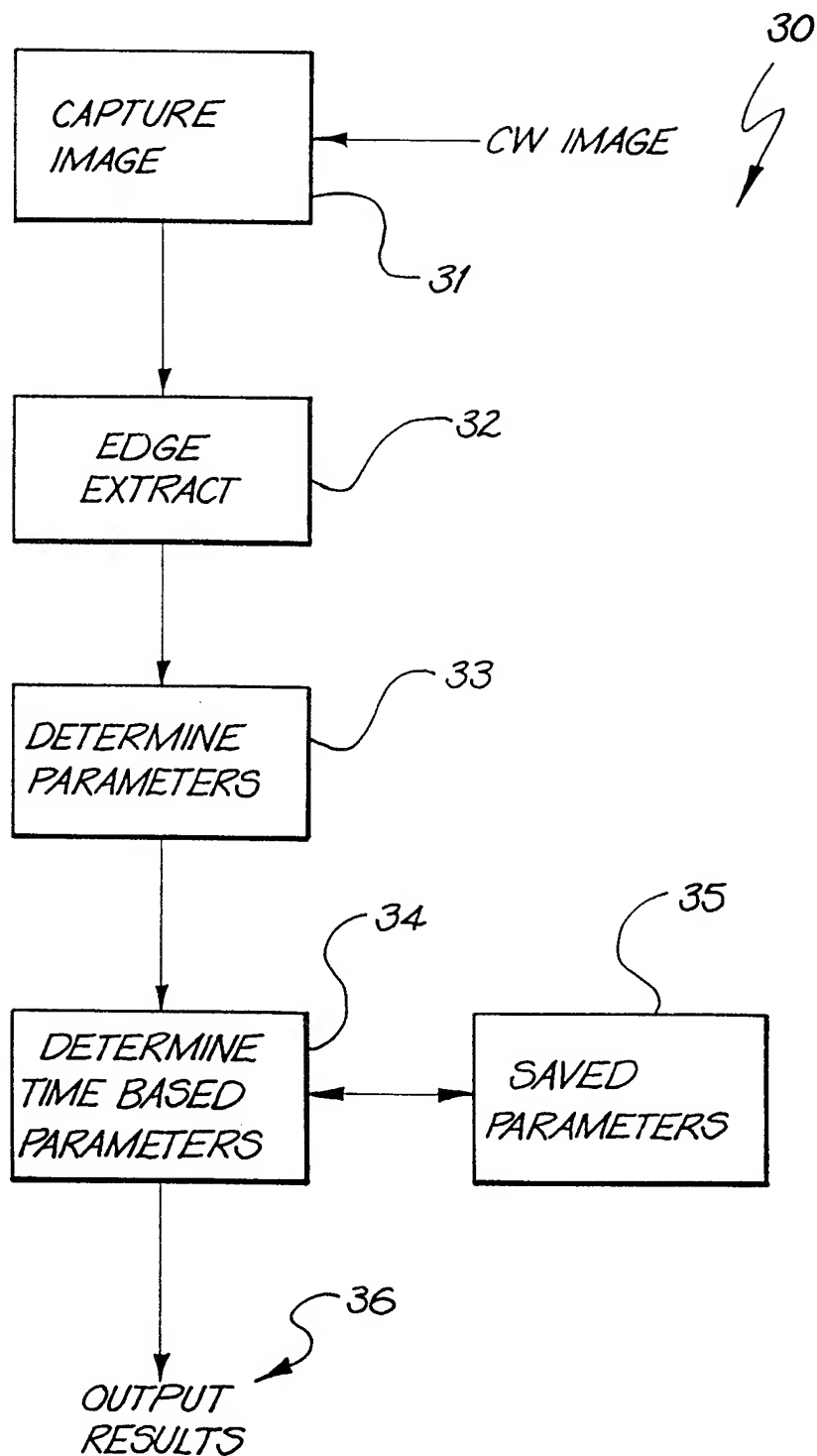


FIG. 7

**FIG. 8**

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00507

**A. CLASSIFICATION OF SUBJECT MATTER**Int Cl<sup>6</sup>: A61B 5/024, 5/029, 8/02, 8/06

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**B. FIELDS SEARCHED**

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WPAT, JAPIO, PubMed Medline

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<i>Clin Physiol</i> 1990 Sep;10(5):463-73 "Cardiac output determined by ultrasound-Doppler: clinical applications." Sjoberg BJ, Wranne B	1-9
X	<i>Br Heart J</i> 1985 Feb;53(2):123-9 "Assessment of cardiac output by the Doppler ultrasound technique alone." Haites NE, McLennan FM, Mowat DH, Rawles JM	1-9
X	<i>Br Heart J</i> 1984 Jan;51(1):54-60 "Determination of cardiac output by Doppler echocardiography." Ihlen H, Amlie JP, Dale J, Forfang K, Nitter-Hauge S, Otterand JE, Simonsen S, Myhre E	1-9

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 268 808 A (British Technology Group) 19 January 1994 See page 5 lines 20-22, page 6 line 12 - page 7 line 14.	1-9
X	US 5 598 845 A (Chandraratna et al) 4 February 1997. See column 6 lines 1-10.	1-9
X	WO 89/04634 (Waters Instruments, Inc) 1 June 1989 See page 11 lines 17-22, page 22 lines 13-24.	1-9
X	EP 172 687 A (Quinton Instrument Company) 26 February 1986 See page 8 lines 6 - 19	1-9
X	US 4 509 526 A (Barnes et al) 9 April 1985 See column 8 lines 9-59.	1-9

## INTERNATIONAL SEARCH REPORT

### Information on patent family members

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GB	2268808	EP	650343	US	5575289	WO	9402069
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		US	4608993				
US	4509526	NIL					
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